

Application No.: 10/796,298
Filing Date: March 9, 2004

REMARKS

Claims 1, 3-38, 74, and 216 have been canceled. Claims 73, 82, and 215 have been amended. New claims 220-239 have been added, which are analogous to canceled Claims 16-35 respectively. No new matter has been added thereby. Claims 73, 75, 77-93, 215, and 217-239 are currently pending, of which Claims 89-90 were previously withdrawn from consideration and of which Claims 220-230 and 234-237 are presently withdrawn from consideration as directed to non-elected species. Thus Claims 73, 75, 77-88, 91-93, 215, 217-219, 231-233, and 238-239 are currently under consideration. Applicant respectfully requests consideration of the arguments below.

Specification

Applicant has amended the specification to clarify that PBT is polybutylene terephthalate. One of ordinary skill in the art would recognize that a PBT resin refers to a polybutylene terephthalate resin and would not understand the acronym PBT to refer to anything else. Thus addition of the term "polybutylene terephthalate" in the specification is not new matter.

Claim Rejections under 35 U.S.C. § 112

Claims 27-29, 34, and 35 have been canceled, thereby rendering the rejection of these claims moot.

Written Description

Claim 73 has been rejected under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. The Examiner suggests that the specification fails to define or provide any disclosure to support the claim limitation "determining the definite quantity of mRNA by dividing the value of sample mRNA determined in step (f) by the percent recovery of spiked control RNA determined in step (g)." Paragraph [0077] of the specification provides that "in preferred embodiments of the present invention a definite quantity of target mRNA can be determined by dividing the values obtained by the TaqMan assay with percent recovery of a dose of spiked control RNA in each sample." One of ordinary skill in the art would understand that the "values obtained by the TaqMan assay" described in this paragraph corresponds to the "value of sample mRNA determined in step (f)" recited in step (h) of Claim 73. One of ordinary skill in

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the art could readily conduct the recited arithmetical division step based on this disclosure. No additional disclosure is needed to carry out this step. Thus Applicant contends that Claim 73 satisfies the written description requirement in its current form.

Claims 215-217 have been rejected under 35 U.S.C. § 112, ¶ 1 as failing to comply with the written description requirement. Claim 215 has been amended to address the Examiner's objection, clarifying that the cDNA formed by extension of the antisense primers goes into solution as a result of displacement by the cDNA formed by extension of oligo(dT). Claim 216 has been canceled, as the limitation therein has been incorporated into Claim 215. Claim 215 now recites that "the cDNA formed by extension of the antisense primers goes into solution as a result of displacement by the cDNA formed by extension of oligo(dT) without heat denaturation." Paragraph [0080] provides support for the "without heat denaturation" limitation, explaining that "the heat denaturing process is completely eliminated." One of ordinary skill in the art would understand that elimination of the heat denaturing process necessarily implies that the cDNA formed by extension of the antisense primers goes into solution without heat denaturation. Thus Applicant contends that Claim 215 satisfies the written description requirement in its current form. Claim 217 recites that "a plurality of different antisense primers for different specific mRNAs are present in the lysis buffer." Paragraph [0080] provides support for this limitation, explaining that "by adding multiple antisense primers for different targets, each gene can be amplified from the aliquot of cDNA." One of ordinary skill in the art would understand that the "plurality of different antisense primers for different specific mRNAs" correspond to the "multiple antisense primers for different targets" described in paragraph [0080]. Thus Applicant contends that Claim 217 satisfies the written description requirement in its current form. As discussed above, Applicant respectfully contends that pending Claims 215 and 217 have sufficient written description support.

Indefiniteness

Claim 73 has also been rejected under 35 U.S.C. § 112, ¶ 2 as indefinite. The Examiner suggests that the limitation "dividing the value of spiked control RNA determined in step (f) by the amount of spiked control RNA obtained in step (d)" has insufficient antecedent basis, as step (f) does not specifically recite a "value" of spiked control RNA and step (d) does not specifically recite an "amount" of spiked control RNA. The Examiner also suggests that the limitation

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“dividing the value of sample mRNA determined in step (f)” has insufficient antecedent basis, as step (f) does not specifically recite a “value” of sample mRNA. Applicant has amended Claim 73 to address the Examiner’s objections and thus Claim 73 should now be in condition for allowance.

Claim Rejections under 35 U.S.C. § 103

Claims 1, 3-12, 15, 27, and 36-38 have been canceled, thereby rendering the rejection of these claims moot.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child, or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner’s attention to the following co-pending applications of the present application’s assignee.

Serial Number	Title	Filed
11/803,663	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	May 15, 2007
11/803,594	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	May 15, 2007

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11/803,593	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	May 15, 2007
11/525,515	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	September 22, 2006
11/376,018	DEVICE AND METHOD FOR HIGH-THROUGHPUT QUANTIFICATION OF MRNA FROM WHOLE BLOOD	March 15, 2006

Applicant understands that the Examiner has access to sophisticated databases available within the USPTO that will allow full access to the file histories of these applications. As such, Applicant respectfully requests that the Examiner review these file histories for any actions that may be relevant to the prosecution of the present application.

CONCLUSION

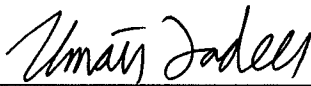
In view of the foregoing, the present application is believed to be fully in condition for allowance. However, should any remaining impediments to allowance be identified by the Examiner, the Examiner is respectfully invited to contact the undersigned attorney at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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